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AGILENT TECHNOLOGIES, INC.
INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.
P.O. BOX 7599
M/S DL429
LOVELAND, CO 80537-0599

EXAMINER	
EPPS, JANET L	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 09/690,173
Filing Date: October 16, 2000
Appellant(s): SHANNON, KAREN W.

Bret E. Field
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-15-02.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 32-48 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

US Patent 5,932,451 Wang et al. 8-1999

Phillips, J. "Antisense RNA Amplification: A linear Amplification Method for Analyzing the mRNA Population from Single Living Cells" METHODS: A Companion to Methods in Enzymology, Vol. 10, (1996), pp. 283-288

(10) Grounds of Rejection

1. The following ground(s) of rejection are applicable to the appealed claims:

2. Claims 32-48 stand finally rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al.

Claim 32, and those claims dependent thereon, recite a kit for use in linearly amplifying mRNA, said kit comprising: an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; and instructions to convert the mRNA to cDNA, and to then transcribe the cDNA into RNA in the presence of a reverse transcriptase that is rendered incapable of RNA-dependent DNA polymerase activity during this transcription step. Claim 41, and those claims dependent thereon, recite a kit for use in linearly amplifying mRNA, said kit comprising (a) an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; (b) an RNAseH- polymerase and (c) an RNAseH+ polymerase.

Although drawn to a kit per the preamble, the instant claims are interpreted as reading on a composition comprising an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence. Since the presence of the instructions in the kit does not material effect the contents of the kit, the instructions are merely considered to be an intended use recitation of the composition of the claims and therefore are not deemed to hold any patentable weight for prior art purposes. The prior art is applied on the basis of the prior art disclosure of the claimed composition. MPEP § 2111.02.

Wang et al. provides kits for use in a method for mRNA amplification, "[w]here such kits may comprise containers, each with one or more of the various reagents (typically in concentrated form) utilized in the methods, including, for example, buffers, the appropriate nucleotide triphosphates (e.g., dATP, dCTP, dGTP and dTTP; or rATP, rCTP, rGTP and UTP), reverse transcriptase, DNA polymerase, RNA polymerase, and one or more primer complexes of the present invention (e.g., poly(T) or random primers linked to a promoter reactive with the RNA polymerase). A set of instructions will also typically be included, where the instructions may be associated with a package insert and/or the packaging of the kit or the components thereof (col. 11, lines 3-15)." In a preferred embodiment of the Wang et al. invention, suitable DNA polymerases will be selected from MMLV reverse transcriptase lacking RNAseH activity and avian reverse transcriptase, and DNA polymerases selected from HTLV-1, HIV, BLV, Taq and Tth (col. 5, lines 29-50).

Wang et al. teach each and every aspect of the instant invention thereby anticipating Appellant's claimed invention.

4. Claims 32-36 and 39-40 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al.

Claim 32, and those claims dependent thereon, recite a kit for use in linearly amplifying mRNA, said kit comprising: an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; and a set of instructions to convert the mRNA to cDNA, and to then transcribe the cDNA into RNA, wheein said kit further comprises at least one polymerase. Claims 39-40 recite the kit according to claim 36, wherein said kit further comprises an RNA polymerase, wherein said RNA polymerase is T7 RNA polymerase.

Phillips et al. discloses compositions for linear amplification of mRNA from a single living cell. The composition used for cDNA synthesis from the mRNA isolated from the living cell comprises a primer comprising a T7 polymerase promoter sequence and an oligo$(dT)_{24}$ sequence; dideoxynucleotide triphophates, and avian myloblastosis virus reverse transcriptase (page 284, col. 1, paragraph 3). The composition used for transcribing antisense RNA from the cDNA produced in the first step comprises T7 RNA polymerase and ribonucleotide triphosphates ATP, GTP, UTP and CTP (page 284, col. 2, paragraph 2). The compositions used in the method of Phillips et al. read on the contents of the kit recited in the instant claims, particularly wherein said kit comprises: an oligonucleotide comprising an RNA polymerase promoter sequence, at least one polymerase, further comprising an RNA polymerase, wherein said RNA polymerase is T7 RNA polymerase.

Phillips et al. teach each and every aspect of the instant invention thereby anticipating Appellant's claimed invention.

(11) Response to Argument

Appellant's arguments filed 10-15-02 have been fully considered but they are not persuasive. Appellants traverse the above rejection of claims 32-48 as anticipated by Wang et al. and claims 32-36, and 39-40 as anticipated by Phillips et al. on the grounds that: "The pending claims are not anticipated by Wang et al. nor Phillips et al. because the claimed elements directed to printed matter carry patentable weight, as a result of the functional relationship between the claimed elements directed to printed matter and the other claimed elements. (Page 5, paragraph 1, of Appellant's Brief) Appellants attempt to substantiate their traversal by citing "The Printed Matter Doctrine," and specifically emphasizing that "[I]t is well settled that patentable weight can be given printed matter only when a novel relationship exists between said printed matter and the claimed structure." (Page 5, paragraph 3). Moreover, Appellants argue that "[T]he Examiner has denied that there is a functional relationship between the instructions for use and the reagents, and has merely asserted that the presence of the instructions in the kit do not materially affect the contents of the kit and are therefore not deemed to hold any patentable weight for prior art purposes." Finally, Appellants argue that the Examiner must prove that there is no such novel and nonobvious functional relationship between the printed matter and the other elements of the invention. (page 6, paragraph 1).

First, contrary to Appellant's assertions, the instructions included in the kits of the present invention are merely descriptive material, and provide only a description of how the other elements of the kit can be used. The presence of the instructions in the kit do not confer any particular structural or functional interrelationships between the other aspects of the kit and the instructions, because the instructions are not capable of causing a functional change in the kit

by their mere presence in the kit. In order for these instructions to result in a functional change, the hand of man must be introduced to execute the manipulations directed by these instructions in order to achieve the intended functional outcome. If the instructions (as in the example of a "data structure" embodied in computer-readable medium, see MPEP § 2106 IV. B. 1(b)) were some how interpreted by some other aspect of the claimed invention, wherein the instructions' functionality is realized, then the "instructions" in that case would hold patentable weight.

The printed material of the kit of the instant invention, do not directly affect any material (i.e. structural) properties of the remaining contents of the kit. Moreover, the instructions merely provide an "intended use" of the remaining contents of the kit, which requires further manipulation of the contents of the kit. In regards to the "intended use" of the contents of kits according to the present invention as set forth in the instructions, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *MPEP § 2115.* The kit, absent the manipulations directed by the "intended use" set forth in the instructions, is clearly anticipated by cited Phillips and Wang et al. references as set forth in the above rejections.

Moreover, in regards to the Appellant's arguments that the Examiner must prove that there is no such novel and nonobvious functional relationship between the printed matter and the other elements of the invention, the presence of the printed matter in the kit of the claimed invention does not impart any particular novel or nonobvious function to the remaining contents of the kit. The prior art references clearly discloses that the contents of the kit can be used in a

method for linear amplification of mRNA as recited in the preamble of independent claims 32 and 41, see for example Phillips et al. page 284, and Wang et al., col. 11. Moreover, the text of these references can be used as instructions (i.e. printed matter) to guide one of ordinary skill in the art to use the disclosed compositions in a method for linearly amplifying DNA. Therefore, there is no evidence that there is any novel or nonobvious functional relationship between the printed matter that provides instruction to use the contents of the kit in a method for linearly amplifying mRNA, and the teachings of either Phillip et al. or Wang et al. which also teach how to use the contents of the kit in a method for linearly amplifying mRNA.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Janet L Epps , Ph.D.
Examiner
Art Unit 1635

JLE
January 7, 2003

Conferees
John L. LeGuyader
Andrew Wang

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

IP ADMINISTRATION
LEGAL DEPARTMENT 20BN
HEWLETT-PACKARD COMPANY
P.O. BOX 10301
PALO ALTO, CA 94303-0890